Complete Summary

GUIDELINE TITLE

Medical management of abortion.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Medical management of abortion. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Oct. 12 p. (ACOG practice bulletin; no. 67). [79 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- On March 17, 2006, the U.S. Food and Drug Administration (FDA) issued a public health advisory to notify healthcare professionals of two additional deaths following medical abortion with mifepristone (Mifeprex) (see below for earlier FDA alerts). The FDA received verbal notification of the deaths in the United States from the manufacturer, Danco Laboratories. At this time FDA is investigating all circumstances associated with these cases and is not able to confirm the causes of death. However, all providers of medical abortion and their patients need to be aware of the specific circumstances and directions for use of this drug and all risks including sepsis when considering treatment. In particular, physicians and their patients should fully discuss early potential signs and symptoms that may warrant immediate medical evaluation. See the FDA Web site for more information.
- On November 4, 2005 the U.S. Food and Drug Administration (FDA) released an update to the July 20, 2005 notice (see below) regarding mifepristone (Mifeprex) and misoprostol. See the FDA Web site for more information.
- On July 20, 2005, Danco Laboratories and the FDA revised the BOXED WARNING and WARNINGS sections of the Prescribing Information, the Medication Guide and Patient Agreement to inform healthcare professionals of four cases of septic deaths in the United States, all reported from California, from September 2003 to June 2005 in women following medical abortion with mifepristone (Mifeprex) and misoprostol. The bacteria causing sepsis has been identified in two of the cases as Clostridium sordellii. The two confirmed

cases of Clostridium sordellii did not have the usual signs and symptoms of an infection. All providers of medical abortion and their patients need to be aware of the risks of sepsis. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Counseling
Management

CLINICAL SPECIALTY

Emergency Medicine
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To present evidence of effectiveness, benefits, and risks of medical abortion and provide a framework for the evaluation and counseling of women who are considering medical abortion

TARGET POPULATION

Pregnant women who are certain about their decision to have an abortion and meet the gestational age criteria for medical abortion (up to 63 days of gestation as calculated from the first day of the last menstrual period)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Counseling patients about early pregnancy options, advantages and disadvantages of medical and surgical abortion, and side effects of medications used for medical abortion
2. Clinical evaluation or ultrasonography before abortion to confirm gestational age
3. Pretreatment laboratory tests (e.g., assessment of hemoglobin or hematocrit and blood typing)
4. Anti-D immune globulin as indicated
5. Prophylactic antibiotics (considered but not specifically recommended)
6. Medical abortion using one of the following regimens:
    - mifepristone plus misoprostol
    - methotrexate plus misoprostol
    - misoprostol alone
7. Non-steroidal anti-inflammatory drugs, or narcotics for pain relief when indicated (considered, but not specifically recommended)
8. A follow-up evaluation including transvaginal ultrasonography to ensure complete abortion
    - Surgical curettage as indicated
9. Surgical abortion in case of medical abortion failure

MAJOR OUTCOMES CONSIDERED

- Complete abortion rates with mifepristone regimens, methotrexate regimens, and misoprostol alone
- Incidence of side effects associated with medical abortions

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and June 2005. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and subspecialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based primarily on good and consistent scientific evidence (Level A):

- Medical abortion should be considered a medically acceptable alternative to surgical abortion in selected, carefully counseled, and informed women.
- The U.S. Food and Drug Administration (FDA)-approved protocol of 600 milligrams of mifepristone orally followed approximately 48 hours later by 400 micrograms of misoprostol orally is safe and effective for medical abortion

through 49 days of gestation (calculated from the first day of the last menstrual period [LMP]).
- Compared with the FDA-approved regimen, mifepristone-misoprostol regimens using 200 milligrams of mifepristone orally and 800 micrograms of misoprostol vaginally are associated with a decreased rate of continuing pregnancies, decreased time to expulsion, fewer side effects, improved complete abortion rates, and lower cost for women with pregnancies up to 63 days of gestation based on last menstrual period.
- A methotrexate-misoprostol regimen is appropriate for medical abortion only in pregnancies up to 49 days of gestation. Women using this regimen may wait up to 4 weeks for complete abortion to occur.
- Mifepristone-misoprostol regimens using 200 milligrams of mifepristone orally and 800 micrograms of misoprostol vaginally are generally preferred to regimens using methotrexate and misoprostol or misoprostol only for medical abortion.
- A patient can administer misoprostol safely and effectively, orally or vaginally, in her home as part of a medical abortion regimen.

The following recommendations are based primarily on limited scientific evidence (Level B):

- Because teratogenicity of medical abortifacients becomes an important issue if the pregnancy continues, patients must be informed of the need for a surgical abortion in the event of a failed abortion.
- Gestational age should be confirmed by clinical evaluation or ultrasonography

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Surgical curettage must be available on a 24-hour basis for cases of hemorrhage, even though less than 1% of women having a medical abortion will need a curettage because of excessive bleeding.
- Pretreatment anti-D immune globulin should be administered if indicated.
- No data exist to support the universal use of prophylactic antibiotics for medical abortion.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendation

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Benefits

- Appropriate provision and management of medical abortion
- Decreased incidence of complications

Specific Benefits

Compared with the U.S. Food and Drug Administration-approved regimen, mifepristone-misoprostol regimens using 200 milligrams of mifepristone orally and 800 micrograms of misoprostol vaginally are associated with a decreased rate of continuing pregnancies, decreased time to expulsion, fewer side effects, improved complete abortion rates, and lower cost for women with pregnancies up to 63 days of gestation based on last menstrual period.

POTENTIAL HARMS

Adverse effects of medications used for medical abortion:

- Bleeding and uterine cramping; nausea; vomiting; diarrhea; warmth or chills, headache, dizziness, fatigue and thermoregulatory problems

- Oral ulcers with methotrexate use, although rare, have been reported in the literature.
- Endometriosis is a rare complication of medical abortions.

CONTRAINDICATIONS

CONTRAINDICATIONS

Medical contraindications to abortion with mifepristone regimens include confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass, intrauterine device in place, current long-term systemic corticosteroid therapy, chronic adrenal failure, severe anemia, known coagulopathy or anticoagulant therapy, and mifepristone intolerance or allergy. Most clinical trials also exclude women with severe liver, renal, or respiratory disease, uncontrolled hypertension, cardiovascular disease (angina, valvular disease, arrhythmia, or cardiac failure), or severe anemia. Misoprostol should not be used in women with an uncontrolled seizure disorder or those who have an allergy or intolerance to misoprostol or other prostaglandins.

Although medical contraindications are infrequent, social or psychologic contraindications to medical abortion are more common. Women are not good candidates for medical abortion if they do not wish to take responsibility for their care, are anxious to have the abortion over quickly, cannot return for follow-up visits, or cannot understand the instructions because of language or comprehension barriers.

QUALIFYING STATEMENTS

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These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Apr (revised 2005 Oct)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 22, 2004. The information was verified by the guideline developer on December 9, 2004. This summary was updated by ECRI on July 21, 2005 following the Food and Drug Administration (FDA) advisory on Mifeprex (mifepristone). This summary was updated by ECRI on March 7, 2006 following the updated FDA advisory on Mifeprex (mifepristone). This summary was updated most recently on April 20, 2006.

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Date Modified: 9/25/2006